Statement-II

The Maternal Mortality Ratio of Andhra Pradesh

(Per 1,00,000 live births)

State	1997-98	1999-01	2001-03
Andhra Pradesh	197	220	195

SOURCE: Registrar General of India.

Clinical trials in Andhra Pradesh

53. SHRI M.V. MYSURA REDDY: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that there is no monitoring mechanism at the Central or State level to oversee the clinical tests in the State of Andhra Pradesh;

(b) if so, the reasons therefor;

(c) whether it has come to the notice of his Ministry that in the name of bio-equivalance or bio-availability tests, the pharmaceutical companies are carrying out clinical tests on innocent people which are resulting in even death of some people in Andhra Pradesh; and

(d) if so, what action his Ministry has taken on such pharma companies?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) Regulation of clinical trials comes under the purview of Central Drugs Standard Control Organization (CDSCO), Dte. General of Health Services and monitoring mechanism exists at Central level. Guidelines and requirements for conducting clinical trials in the country are specified in Schedule-Y of Drugs and Cosmetics Rules, 1945 and it requires that the clinical trial is carried out as per Indian Good Clinical Practices (GCP) Guidelines issued by Dte. General of Health Services.

Before conduct of clinical trial the investigator is also required to give undertaking that he will maintain adequate, accurate records and make those records available for audit / inspection (Oversee) by the sponsor, Ethics Committee, Regulatory Authority or their authorized representatives.

As per clause 3.1.13 of Indian GCP guidelines the sponsor should ensure that clinical studies are adequately monitored and they must appoint adequately trained monitor to supervise the clinical trial.

Further, clause 3.1.14 of said guidelines requires that sponsor should perform audit as a part of Quality Assurance system. Auditor should document their observations which should be made available to the Regulatory Authorities when called for.

(c) and (d) Bio-equivalence / Bio-availability studies of new drugs are permitted to be carried out in the country in accordance with the Drugs and Cosmetics Rules. The studies are required to be conducted as per the GCP guidelines.

There was a report of death of a subject who was involved in a Bioequivalence study in a centre in Hyderabad. As per the information received from the bioequivalence study centre, the subject was administered the first dose of a drug on 26 November 2008 and was discharged on 28 November 2008. He submitted another blood sample on 29 November 2008. As advised by the Centre the subject visited the center again on 5th December 2008 for second dosing planned on 6th December 2008 and complained of chest pain and breathlessness. After preliminary treatment by the in house Doctor of the centre, the subject was shifted to nearby Hospital. As per the information received from the hospital cause of death could not be arrived as the patient was brought dead.

Medical care to patients suffering from chronic diseases

54. SHRI VIJAY JAWAHARLAL DARDA:
SHRIMATI SHOBHANA BHARTIA:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government is aware that the number of people suffering from chronic diseases are rapidly increasing in the country;

(b) if so, whether the existing health-care facilities are not found adequate to treat patients of such chronic diseases in the country;

(c) if so, the facts and details thereof; and

(d) whether Government proposes to improve its medicare facilities throughout the country and also to ensure that the patients suffering from chronic diseases are treated timely?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) Yes, Sir. Reports indicate that the number of people suffering from chronic diseases is increasing in the country.

(b) to (d) Healthcare services for different ailments are available to the people throughout the country though the Government health facilities at Primary Health Center, District Hospital, State Medical Colleges and National level Institutions. The facilities are reviewed from time to time under various programme of National Rural Health Mission and the National Programme on Diabetes, Cardiovascular diseases and Stroke (NPDCS). An outlay of Rs. 1660.50 crore has been provided for the NPDCS during the 11th Five Year Plan. NPCDS have been initiated in 10 districts in 10 States in pilot phase.

Expansion of health-care facilities in Delhi

†55. SHRI JAI PARKASH AGGARWAL: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government has any proposal for expansion of health-care facilities in Delhi before the commencement of Common Wealth Games in the year 2010;

(b) if so, the number of dispensaries, hospitals and trauma care centres proposed to be set up and upgraded; and

†Original notice of the question was received in Hindi.